HIV TESTING AND INFORMED CONSENT: A STUDY OF PHYSICIAN BEHAVIOR

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by

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ABSTRACT

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The problem of the Acquired Immunodeficiency Syndrome (AIDS) epidemic and the advent of large-scale testing for antibodies to the Human Immunodeficiency Virus (HIV) present unforeseen burdens to the creation of a beneficial doctor-patient relationship and confuse already difficult issues of confidentiality, duty to treat, and consent.

This thesis investigates the role of informed consent in the context of HIV testing. Appeals have been made by several experts for informed consent before ordering HIV tests, but what this entails is unclear. No other blood test has elicited calls for such stringent disclosure by the health care provider.

The legal doctrine of informed consent has evolved rapidly over the past 25 years, and a relative consensus of the physician's duty has emerged: a physician must disclose, according to varying standards set either by the "community of physicians" or a "reasonable lay person", the nature, benefits, risks, alternatives, and possible negative consequences of a proposed procedure.

To determine whether physicians act in accordance with this legal standard in the case of HIV testing, an empirical study of the consent process was undertaken at Yale-New Haven Hospital. Twenty physicians ordering HIV tests over a two-week period were interviewed to assess the level of disclosure usually practiced when ordering HIV tests. Few physicians were found to have disclosed the relevant benefits (25% of physicians) or risks (30% of physicians) of HIV testing, and, using a created measure of disclosure, only three physicians (15%) were found to disclose at least an "average" amount of information in their usual practice.

Given this general underreporting of information, steps should be taken to educate health care providers as to the relevant benefits and risks of HIV testing. The necessity of adequate disclosure should be emphasized. A commitment to protecting the interests of patients who undergo HIV testing through the communication of relevant information can help stave off unnecessary patient harm and resultant litigation.

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I. INTRODUCTION.

Life is a battle in which we fall from
wounds we receive in running away.

William L. Sullivan

The epidemic of the Acquired Immune Deficiency Syndrome (AIDS) has been called, by some, the most pressing medical issue of the twentieth century (Gallup poll conducted October 1987, 1987). Worldwide, more than 70,000 cases have been reported to the World Health Organization by 127 countries (Von Reyn & Mann, 1987) and in the United States, by the end of 1987, some 27,909 were reported to have died, 56% of the nearly 50,000 reported cases (Centers for Disease control, 1987b). According to federal health officials, one to one-and-a half million Americans are now asymptomatic carriers of the Human Immunodeficiency Virus (HIV), the causative agent in AIDS. Ill-prepared to handle these projected millions, our medical system in the coming years will have to stretch and adapt in ways we can only begin to estimate. Projections of the economic toll alone have been staggering (Cole & Lundberg, 1986).

Even more profound may be the epidemic's ultimate effect on the personal relationship developed between patient and practitioner. Already well-discussed issues of autonomy, beneficence, non-maleficence and justice have taken on new and different meanings in the context of AIDS. Surprisingly, little has been done to study the actual workings of the doctor-patient relationship in this context.

This study will assess how physicians, in their interactions with patients, are responding to one facet of the epidemic: the use of a blood test to determine whether a patient has been exposed to the HIV. Unlike routine blood tests, which normally do not require the explicit consent of the patient tested, the anti-HIV antibody test (hereafter called the HIV test), because of its unique medical and social risks, has been deemed different enough to require such consent (Bayer *et al.*, 1986). Many institutions will perform the test only after consent has been documented (Henry *et al.*, 1988).

This raises a host of questions about the use of informed consent: Are physicians in fact obtaining informed consent? For what reasons are physicians ordering the HIV test? What are the risks and benefits of the test that they are explaining to their patients? Who should be responsible for obtaining consent? Can physicians, who are not deemed "experts" in social or policy issues, be held liable for remote social risks not explained to patients? Should

physicians have to include refusal of medical treatment (perhaps their own) as one of risks of the HIV test?

This thesis is divided into two parts: the first is a review of the ethical and legal basis for informed consent (as it particularly applies to HIV testing), and the second is an empirical study of the actual use of informed consent by physicians ordering HIV tests. The empirical section consists of the results of some 20 semi-structured interviews that were conducted with physicians after obtaining consent for an actual HIV test. These interviews are intended to address some of the questions asked above.

A. THE AIDS EPIDEMIC.

On June 5, 1981, the Centers for Disease Control published a report from Los Angeles (Centers for Disease Control, 1981a) describing five new cases of *Pneumocystis Carinii* pneumonia in young homosexual males, a disease thought to inflict only those with a severe underlying immune disturbance. A month later, on July 3, 1981, another report was issued (Centers for Disease Control, 1981b) describing the appearance of a rare malignancy, Kaposi's sarcoma, in a similar population of patients.

AIDS is now known to be the extreme clinical presentation on the spectrum of infection with HIV, and is technically a defined "syndrome" (the definition of which has recently changed [Centers for Disease Control, 1987d]), rather than a single "disease". The period of time between infection with HIV and the development of symptoms (if any) can be many years (Curran *et al.*, 1988).

HIV is known to infect various cells in the body, but primarily causes death through the infection and ultimate incapacitation of the immune system, allowing so-called "opportunistic" infections - infections normally warded off by a competent immune system - to take root (Fauci, 1988).

The virus is believed to be transmitted in primarily three ways: during sexual contact; through parenteral exposure to blood and blood products; and from mother to child (Curran *et al.*, 1988). There have been a few reports

of transmission of the virus to health care workers through both parenteral and mucous membrane exposure (Centers for Disease Control, 1987d).

Given these modes of transmission, infection with HIV in the United States has remained confined to primarily two groups: Homosexual or bisexual men (65%); and intravenous drug users (17%). One percent of AIDS victims have been hemophiliacs, and 2% have been transfusion recipients (Curran *et al.*, 1988).

There is no current vaccine available to prevent infection with HIV, as well as few well-studied treatments for the primary infection. There is, at present, no cure for AIDS.

B. ANTI-HIV ANTIBODY TESTING.

With the discovery of an infectious etiology, AIDS researchers turned to the development of a routine blood test that would detect the presence of HIV infection. In March of 1985, the Food and Drug Administration (FDA) announced the first licensing of a commercial test that would detect the presence of antibodies to virus particles in blood, allowing the mass screening of donated blood and plasma to prevent transfusion-related infection.

Clinical use of the HIV screening test began in April, 1985, and its use since that time has grown to include screening at clinics and hospitals, screening of distinct population groups (*e.g.*, military recruits), and large scale anonymous testing at so-called "alternative" sites, developed largely out of the fear that high-risk individuals would seek testing by donating blood (Centers for Disease Control, 1986).

The first test developed to detect the presence of HIV is known by the generic name of Enzyme-linked Immunosorbent Assay (ELISA), which detects the presence of antibodies normally stimulated by the virus (Saxinger *et al.*, 1983). Because this test originated from the desire to protect the nation's blood supply, the goal was to detect every truly-infected unit of blood donated; thus, the specificity of

the test was sacrificed to maintain a high sensitivity.[1]

A recent report from the Centers for Disease Control evaluates the sensitivities and specificities of currently used ELISA tests (Centers for Disease Control, 1988). Sensitivities and specificities both greater than 99.0% are reported, a figure that is variable depending on the quality of the laboratory engaged in routine HIV screening. The normal procedure is for a "reactive" (or positive) ELISA test to be repeated, thus minimizing this laboratory error. A specificity greater than 99.0% poses no problems when screening groups with a high percentage of infected individuals, but the proportional number of falsely-positive individuals becomes larger in screening low-risk groups, sometimes far outnumbering the true-positives detected (*The New York Times*, Nov. 30, 1987).

Because of the medical and social consequences of being labeled HIV antibody "positive", the Public Health Service has recommended, in addition to repeating the initially positive ELISA test, the use of an additional confirmatory test (Centers for Disease Control, 1987a). Most laboratories are using the Western Blot (Tsang *et al.*, 1983), a technique that is dependent upon the subjective interpretation of laboratory personnel in identifying a positive or negative result. If the manufacturer's strict interpretive criteria are used, the probability of either a

[1]Sensitivity is the probability that the test result will be reactive if the specimen is a true positive; specificity is the probability that the test will be non-reactive if the specimen is a true negative.

false-positive or a false negative result is extremely small (Centers for Disease Control, 1988).

However, in clinical use on persons at low risk, as many as 15-20% of test results have been reported as "indeterminate". Recommendations for standardization of the use of the Western Blot have been published (Association of State and Territorial Public Health Directors, 1987), but the extent of adherence to these is unknown. The problem of accuracy is compounded by the fact that many laboratories use, for expense reasons, a Western Blot test unlicensed by the FDA, thus escaping the rigorous scrutiny and standardization that licensed tests must meet (Centers for Disease Control, 1988). A demonstrable false-positive rate of <0.001% can be achieved with sequential ELISA and Western Blot testing if the manufacturer's guidelines and other quality controls are adhered to. A nationwide evaluation of the use of HIV antibody testing has been initiated by the CDC's Training and Laboratory Program Office and Center for Infectious Diseases in an attempt to address these issues (Performance evaluation program, 1987).

In addition, the CDC has stressed the importance of having a "clear understanding of the significance of the test results and the potential pitfalls of the testing process" (Centers for Disease Control, 1988).

It is important to stress that the HIV antibody test was developed to detect infection (via the presence of indicator proteins) in donated blood; its use in diagnosing

and treating patients is more limited. One author (Bayer *et al.*, 1986) has noted several uses of the test in a clinical setting: it allows clinicians to monitor the potential infectiousness of their patients (antibody-positive individuals are presumed infectious); it may be useful in establishing risks to the patient when contemplating immunosuppressive therapy; it may provide epidemiologists with data to track the disease and to describe its natural history; and, finally, and perhaps most importantly, it may be used to provide information to individuals supporting their voluntary modifications of behavior.

The use of the HIV antibody test to screen certain large populations has been suggested. Recent Illinois legislation now requires HIV tests of all couples before marriage (Wilkerson, 1988), straining the state's laboratory facilities, and driving some couples to cross state lines to be married. The number of applications for marriage in Cook County has dropped by more than 50% since the inception of testing. Only two states, Illinois and Louisiana, currently require such premarital HIV testing.

Screening of all current members of, and applicants to, the US Armed Forces began approximately two years ago (Pentagon AIDS Testing Finds 5,890 Infected, 1988). During that time, the Defense Department has tested nearly four million people, and has identified 5,890 as HIV antibody positive. The current detection rate of 1.5 cases of

infection per 1000 people screened, has remained constant throughout the duration of the testing.

In a controversial recommendation, Surgeon General C. Everett Koop recently recommended screening every student at a major urban university (student body of approximately 25,000) in order to determine the epidemiology of HIV infection in college-age adults (Jamieson, 1988). The testing would be anonymous, and the students tested would not be provided with the results.

Dr. James O. Mason, director of the Centers for Disease Control, announced in December, 1987, a plan to randomly test more than 50,000 households in 30 major cities throughout the nation, in an attempt to determine how quickly the virus is spreading (Boffey, 1987). Blood samples would be collected on an anonymous basis at selected hospitals and clinics for sexually transmitted diseases, drug addiction, tuberculosis, pregnant women and family planning. When this testing becomes operational in May, 1988, some 1.6 million people will be having their blood tested annually for the presence of HIV antibody. Combining this with other large-scale screenings of population groups already under way, over 7.7 million people will be having their blood tested annually by mid-1988.

These current and future testing programs show that the social problems produced by the HIV testing dilemmas only promise to grow. The future implications of seropositivity, both medically and socially, are unknown, but with such a

large group of Americans undergoing routine HIV testing, it seems prudent to investigate the decision-making process in greater detail. Historically, medical practitioners have not always retained their patients' interests above their own (Zuger & Miles, 1987), and thus both patient and doctor need information as to the most appropriate course of action in an environment where fear and intolerance have the potential to dominate.

C. GOALS OF THIS STUDY.

The primary purpose of this study is to investigate the nature of decision-making in the setting of HIV testing, and to do this, the problem has been broken into two parts.

The first is to view the process of informed consent in relation to its use in other clinical settings. Through the development of ethical and legal theory, there has emerged a relatively uniform doctrine of informed consent which serves to guide physicians and their patients in decision-making. The principles that have evolved in the law can be applied to the setting of HIV testing (although this, too, is arguable). The first part of this study is therefore a retelling of the history of informed consent, placing the current problem in its historical and legal context.

The second purpose of the study is to assess the actual behavior of physicians in working out a decision to test for HIV. The essence of an "informed" consent from the physician's perspective consists of disclosure, and therefore, the scope of risk and benefit disclosure, especially when those risks and benefits are uncertain and controversial, is a necessary item of investigation. Do physicians behave in a uniform manner when ordering HIV tests? Is there a uniform level of disclosure - a consensus of the community of physicians - which a physician ordinarily should follow in disclosing information regarding HIV testing? What items of disclosure are necessary for an

informed consent? To begin to answer these questions, one needs to enter the realm of actual clinical decision-making, and thus the second part of this study is a retrospective sampling of actual disclosure conversations as reported by the physicians themselves.

II. THE FOUNDATIONS OF INFORMED CONSENT IN ETHICAL THEORY AND LEGAL HISTORY.

Arguments for the doctrine of informed consent can be found in both ethical theory and legal history, and it is within the realms of these two disciplines, law and morality, that the vocabulary of informed consent has been framed. Although by no means separable, these two approaches have, in recent years, come to focus on different players within the doctor-patient relationship: the law centering on the duties of physicians and, necessarily, the liabilities resulting from failure to discharge those duties; and ethical theory centering on the rights of patients.

In this section, I will present the basic ethical principles upon which the theory of informed consent is built, and in the following section, I will show, through landmark cases, how the law has come to shape the actual workings of informed consent.

A. THE ETHICAL BASIS OF INFORMED CONSENT.

Ethical theory has as its *a priori* postulates certain principles upon which applied ethical reasoning takes place. Although the creation and definition of these principles is a controversial matter, Beauchamp and Childress (1983) have outlined what they consider to be the four essential principles of ethical discourse: the principles of autonomy, beneficence, nonmaleficence, and justice. When, in a given circumstance, these principles conflict, it is through weighing and balancing, the substance of ethical reasoning itself, that one arrives at an informed conclusion.

In various discussions on the contributions of these principles, it is clear that one principle, the respect for autonomy, has contributed more to the philosophical groundings of informed consent than any other. Derived from the Greek words *autos* (self) and *nomos* (rule or law), autonomy has come to refer to personal self-governance: the personal rule of the self, based on an adequate understanding, that remains free from the controlling influences of others. As Immanuel Kant (1948) expressed, autonomous persons are to be treated as ends in themselves, determining their own destinies, and are not to be treated merely as a means to the ends of others. In the context of informed consent, it is autonomous choice, the exercise of

capacities to be independent and in control, with which we are most concerned.

Faden and Beauchamp (1986) properly point out the limits in defining the precise obligations that the principle of autonomy entails in the consent context. Where independent choice conflicts with public good and with the consumption of scarce societal resources, or where it leads to harm to another, other principles must come into play.

The principle of beneficence is most often given as a second supporting justification for informed consent. Faden and Beauchamp (1986) describe four elements to the principle of beneficence: 1. One ought not to inflict evil or harm. 2. One ought to prevent evil or harm. 3. One ought to remove evil or harm. 4. One ought to do or promote good. Thus, the principle of beneficence is often seen as encompassing the avoidance of harm, as well as the active doing of good. In fact, the celebrated maxim of medical ethics *primum non nocere* - "above all, do no harm" - reinforces the idea that beneficence, in medicine, is demonstrated by avoiding harm. Practically speaking, all physicians know and realize that harm must, at times, be inflicted for the good of the patient, and it is this balancing of inflicted harm with potential good that must be maintained.

In the informed consent context, it is the balancing of the professional's desire to do good, or avoid harm, with the patient's own understanding of the good or harm

involved, that must be maintained. The concept of medical paternalism provides justification for the overriding of patient decisions in cases where the good of the patient is at stake.

Many legal cases have allowed "therapeutic privilege", which is the purposeful withholding of information by the physician, as an exception to patient autonomy. Inherent in the "therapeutic privilege" is the idea that, given certain circumstances, full disclosure can actually harm, rather than help, the patient. Whole treatises (see VanDeVeer, 1986) have been written in an attempt to define when, or if, this privilege should be involved. Although authors have spent considerable time illuminating the assumptions underlying the perceived need for withholding information, the legal system has continued to support physician judgement in deciding when to withhold.

Authors have differing opinions as to what other principles play a predominant role in the issue of informed consent. Faden and Beauchamp (1986) discuss the principle of justice, by which they mean the fair and equitable treatment of all persons. Issues of distribution of medical resources and the validity of claims to a right to health care, are often given as examples of how the principle of justice enters into ethical discourse. In the context of consent, it is often broader questions of research on human subjects where this principle enters in. Can prisoners give valid consent to participate in research when incarceration

itself affects autonomous decision-making? Are the burdens of research equitably distributed when we use a ready pool of volunteers (people institutionalized for one reason or another), or when financial remuneration is offered as an incentive to participation?

Other authors, Beauchamp and Childress (1983), discuss the principle of utility in the context of informed consent. Utility is the idea that something should be done, not for the right or wrong involved, but because social benefit, outweighing harm, can be derived from such action. Requiring consent, they argue, will maximize social good - it will protect and benefit patients and professionals alike, it will alleviate public fears (especially about research), and it will encourage self-scrutiny by physicians and investigators. This is opposed to the idea that autonomy guarantees personal decision-making regardless of the outcome. Robert Veatch has argued that autonomy justifies informed consent "not to facilitate social benefits, but as a check against them", since persons have rights to information and decision-making that are independent of the social utility involved.

In conclusion, we see that the philosophical basis for informed consent resides primarily in two central principles: the concept of personal autonomy; and the desire to promote good, and avoid harm, in the practice of medical care. Issues of justice and social utility are, in turn, balanced against these primary principles.

B. THE LEGAL DEVELOPMENT OF THE DOCTRINE OF INFORMED CONSENT.

1. COMMON LAW AND THEORIES OF LIABILITY.

Legal doctrines arise in significant part from moral principles. However, the law faces its own internal limits: the structure and function of the adversary system, the problems of enforcement and remedies, and the practical issues arising from the use of case-by-case adjudication. Accordingly, the development of the legal doctrine of informed consent has carried with it the particularities of the branch of law known as common law. Common law is that body of unwritten guidelines, fashioned and molded over time through individual court opinions.

In common law, the moral principle of autonomy has become embodied in the battery theory of liability. This is the principle under which a person is held liable for the unauthorized physical contact of another person, and derives from the belief that all people have the right to decide whether they wished to be "touched". It is important that there need not be any injury sustained in this unpermitted contact for a successful claim of battery to be brought - it is the unconsented act itself that is wrong. The moral principle of autonomy has become, under the theory of battery, the legal right to self-determination.

In addition, we see the grounding of consent in another theory of liability in common law - the negligence theory of liability. Under negligence, one is held liable when, in the course of discharging a legal duty to another, some injury is brought about by unintentional or careless action, or through the omission of an act. Often, this duty is measured by the standard of the reasonable person, an abstraction representing the community consensus of acceptable behavior. Medical malpractice is one type of professional negligence, and it is by the standard of the reasonable physician that one is judged under the negligence theory of liability.

2. CONSENT AND BATTERY LIABILITY.

The legal history of consent really begins in the early twentieth century. There are some cases before this time that deal peripherally with the issues of consent, but it is clear that this was not an intended concern of the law, and that nobody - judges, doctors, and the public alike - had ideas that doctors should be informing patients, in an open and complete manner, before initiating treatment. See *Slater v. Baker and Stapleton (1767)*, *Carpenter v. Blake (1878)*, and *Wells v. World's Dispensary Medical Association* (1890) as examples of consent as a peripheral issue.

There are two landmark cases in the early twentieth century, *Pratt v. Davis (1906)* and *Schloendorff v. The Society of the New York Hospital (1914)*, that are credited with establishing the battery theory of liability as a means of redressing the lack of patient consent.

In the *Pratt* case, a forty year old epileptic woman solicited a Dr. Pratt for advice and treatment concerning her chronic condition. After his examination, Dr. Pratt concluded that Mrs. Davis' ovaries and uterus had to be removed, which he subsequently did, without informing his patient of what was going to be done.

In his testimony, Dr. Pratt stated of Mrs. Davis, that he "wished her to come to the operating room without violence", and so had spoken only of his intention to repair some cervical and rectal tears. He had done this, Dr. Pratt

insisted, because of his openly admitted belief that "when a patient places herself in the care of a surgeon for treatment without [express limitations] upon his authority, she thereby in law consents that he may perform such operation as in his best judgement is proper and essential to her welfare".

The court resoundingly rejected this idea, stating that physicians and surgeons were forbidden from violating the fundamental and inviolable right of bodily integrity, without the express consent of the patient. The assertion of implied consent was an inadequate argument, and could be claimed only in certain extreme situations, primarily unforeseeable emergencies.

In the succeeding and more influential case of *Schloendorff v. The Society of New York Hospitals* (1914), a female patient had consented to an examination under anesthesia for uterine fibroids, but had explicitly stated that she wanted no operation performed. The surgeon ignored the patient's request, and proceeded with a hysterectomy. Justice Benjamin Cardozo, in his classic opinion, eloquently laid out the rationale for informed consent as an expression of patient self-determination:

> Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages.

This opinion had a tremendous impact in the developing consent law. It served to focus attention on the idea that any unauthorized treatment by a physician constituted a battery, regardless of the skill with which the treatment was administered or any beneficial effect the treatment may have had.

As Katz (1984) points out, the opinion was deficient in addressing practical concerns of consent, such as the proper limits of physician disclosure, but the firm grounding of self-determination as a legal basis for consent - echoing the previously described moral principle of autonomy - was assured.

3. "INFORMED" CONSENT AND NEGLIGENCE LIABILITY.

The next major development in consent law did not occur until forty years later. Until the case of *Salgo v. Leland Stanford Jr. University Board of Trustees* (1957), most consent cases cited the opinion of Justice Cardozo in *Schloendorff v. The Society of New York Hospitals* (1914) that physicians had a duty to obtain the minimal consent of a patient before "invading" their person. But now, a new element was added - the idea that a physician had to duty to disclose certain information, and that without such disclosure, consent cannot be considered valid.

In 1954, Martin Salgo underwent translumbar aortography for a suspected obstruction of the abdominal aorta. The following morning, he awoke paralyzed from the waist down. He claimed that the paralysis was due to the negligent performance of the angiography by his physicians, but then appended a claim that the physicians had failed to warn him of the risks inherent in the procedure.

Justice Bray spoke for the court when he upheld the plaintiff's claim, stating that physicians had the duty to disclose "any facts which are necessary to form the basis of an intelligent consent by the patient to proposed treatment".

For the first time, the phrase "informed consent" was used, denoting this new requirement for physician-disclosed information: "In discussing the element of risk a certain

amount of discretion must be employed consistent with the full disclosure of facts necessary to an informed consent."

Thus, physicians were now not only required to inform patients that they were to be "touched" (avoiding a claim of battery), but they were also to inform patients of the attendant benefits, risks, and alternatives to such "touching". The opinion was confusing in the fact that Justice Bray left it up to the discretion of the physician to decide what should be deemed "full" disclosure. Katz (1984) considers this exemplary of the ambiguity which would pervade succeeding opinions in their inability to resolve the dilemma of how to disclose.

In addition, the opinion in the *Salgo* case did not ground the new requirement for "informed" consent in either battery or negligence law. This case was brought as a negligence claim, although the cases cited as supporting the opinion were all battery cases (including *Schloendorff*). While the court was adding a new element to consent as it had been grounded in battery law, it was allowing for the evolution of a doctrine that would combine both battery and negligence theories of liability into a single unified theory of consent.

This opportunity to formulate a doctrine of consent in both battery and negligence was not realized in subsequent decisions. Instead, the courts siezed upon the late entry of negligence liability as a justification for consent and

expanded the role of the professional in determining what "informed" consent should mean.

4. THE "PROFESSIONAL PRACTICE" STANDARD.

Whereas *Salgo* had combined elements of both battery and negligence in its opinion, the Kansas Supreme Court, in *Natanson v. Kline* (1960), moved the justification for consent much more squarely into the camp of negligence liability.

Irma Natanson had suffered extensive injuries from cobalt treatment used in conjunction with mastectomy to treat her breast cancer. She sued her radiologist, Dr. John R. Kline, claiming that he had been negligent in both administering the treatment, and in failing to inform her of the consequent risks and hazards.

Thus, the patient had alleged negligence only, and the court upheld this, stating (as in *Salgo*) that physicians had the obligation to "disclose and explain to the patient in language as simple as necessary the nature of the ailment, the probability of success or of alternatives, and perhaps the risks of unfortunate results and unforeseen conditions within the body."

The standard for determining the adequacy of disclosure was adopted from existing negligence theory: "The expert testimony of a medical witness is required to establish whether such disclosures are in accordance with those which a reasonable medical practitioner would make under the same or similar circumstances." This has become known as the

"professional practice" standard, and is generally the standard adhered to in most jurisdictions today.

The law had thus found an easy way to determine the extent of disclosure. The "professional practice" standard left the matter to physicians themselves, thus relieving the courts of criticisms that judges or juries were making "medical" decisions.

Many drawbacks to the "professional practice" standard have been cited (Faden & Beauchamp, 1986). First, the standard assumes that there exists a consensus within the community of physicians. This is difficult to prove. Second, the standard tends to perpetuate mediocrity amongst physicians. It allows doctors to legally give inferior or insubstantial information to patients justifiably, since that is the level of information that all physicians are disclosing. And finally, the chief objection of the standard is that is tends to undermine patient autonomy, which many hold to be the primary purpose of informed consent.

5. THE "REASONABLE PERSON" STANDARD.

Our remaining landmark case in consent law, *Canterbury v. Spence* (1972), established a new standard for physician disclosure, leading to the overthrow of the "professional practice" standard in certain jurisdictions.

In 1959, a young patient underwent a laminectomy for severe back pain. Twenty four hours after the operation, the patient fell out of his hospital bed and immediately suffered paralysis below the waist. He claimed to not have been warned of the 1% risk of paralysis that accompanies a laminectomy.

Justice Robinson of the Washington D.C. Court of Appeals, in finding for the plaintiff, reiterated the principle of self-determination in decisions regarding the dispensation of one's own body. Although the court upheld the plaintiff's negligence claim, it struck down the standard by which disclosure was to be judged. Justice Robinson could not agree that "the patient's cause of action is dependent upon the existence and nonperformance of a relevant professional tradition". The new standard was to consist of that information necessary for a "reasonable person" to make an informed decision.

Thus, the court for the first time rejected the unquestioned authority of the medical professional in favor of a fuller understanding of doctor-patient communication. Physicians were deemed to have no more insight than a

reasonable lay person, once the appropriate medical information was communicated, in coming to an appropriate decision. Note, however, that this is not a "subjective" standard: that is, physicians were not required to disclose according to their particular patients' informational needs and desires. Instead, "on the basis of his medical training and experience [the physician] can sense how the average, reasonable patient expectably would react." The significance of any particular risk or benefit is measured in terms of what significance a "reasonable" person would attach to the particular risk or benefit, rather than the particular patient in question.

Proponents of this standard of disclosure would generally regard the patient's autonomy (as opposed to the physician's beneficence) as deserving of more protection. Others have cited problems with this standard: Given the difficulty in ascertaining what a "reasonable" person might require, the standard has been deemed impossible to satisfy. Courts have so far been unable to articulate what the standard should mean (Faden & Beauchamp, 1986). Thus, physicians have been left with little guidance in formulating a standard of disclosure.

The doctrine of informed consent has had a rapid evolution in the law. In a short amount of time, consent has moved from mere "nodding of the head" to a physician's proposed action, to an elaborate measure of specific items

of disclosure. Whether these developments have had any real effect on the way doctors communicate with patients is another matter altogether. Certainly the awareness of patients' informational needs has changed: no more can physicians regard medical decisions as solely within their province.

C. HIV TESTING AND INFORMED CONSENT.

Given the social and medical risks of having an HIV test performed, many authors have urged that informed consent be obtained before the test is ordered (Bayer et al, 1986; Goldsmith, 1987; Eickhoff, 1988; Sherer, 1988). There has been, however, no explicit guidelines as to what "informed consent" in the context of HIV testing really means.

No litigation has yet arisen merely on the claim of lack of informed consent before HIV testing. Personal communication with the Lambda Legal Defense Fund and the National Gay Rights Advocates, both which are organizations heavily involved in HIV-related litigation, turned up no pending cases involving informed consent and HIV testing.

The American Psychiatric Association, in their Position Statement on AIDS (1986), has given the most complete statement to date on HIV testing and informed consent. They state:

> The confidentiality of persons undergoing HIV serologic testing for clinical and research purposes should be protected, and all information obtained including identifying data and test results should be used only for the purposes explicitly stated in the informed consents and releases of information. When testing is performed for clinical or research purposes, attention to the psychiatric implications must be considered pre- and post-testing and the possible adverse consequences of serologic testing be explicitly stated in the informed consent.

Thus, this statement would seem to imply that the consent process should, at a minimum, include a discussion of the purposes, the psychiatric implications, and the possible adverse consequences of HIV testing. What follows is a discussion of these relevant adverse consequences.

The HIV test is a procedure performed by routine venipuncture, and thus carries with it the known medical risks of phlebotomy (Robb, 1985). Although serious nerve compression and even cardiac arrest have occurred, less dire consequences such as hematoma, pain, swelling, and changes in sensation were more frequently reported. These risks are considered of such minimal significance that they need not be reported to patients (in the clinical setting).

The psychological risks of HIV testing have been well documented (Nichols, 1987; Holland & Tross, 1985). These include anxiety, minor and major depressions, and suicide attempts (Temoshok *et al*, 1987; Beckett *et al*, 1986). In many of these cases, the effects may be severe, immediate, and irreversible.

Other problems have arisen in the area of employment. Loss of jobs, or refusal of employment, has occurred following disclosure of test results or even disclosure of seeking the test (Stempel *et al.*, 1987; Douglas, *et al.*, 1987). Pierce & VanDeVeer (1988) report that in New York City, some local leaders have called for the mandatory screening of all teachers, health care workers, and barbers in order to prevent the employment of those that carry the

HIV. Similarly, in Dade County, Florida, county supervisors have promoted the screening of all food handlers so that those who are antibody positive could be excluded from jobs.

These reports, along with the above mentioned screening by the Defense Department of all members of the armed forces, show that calls for exclusion in the workplace for those infected with HIV will continue to be a possible adverse consequence of HIV testing.

Similar problems revolve around the health and life insurance industries. Two states, California and New York, have moved to prohibit the use of HIV testing to screen potential insurees (Sullivan, 1988). In eight states - Minnesota, Connecticut, Indiana, Florida, North Dakota, Montana, Wisconsin, and Nebraska - pools have been created to guarantee coverage to people whose initial applications for health insurance are refused because of risk factors or preexisting health conditions, with twenty other states considering similar legislation. With the number of new AIDS cases rising dramatically, the costs entailed will also rise, meaning that this issue will only become more heated.

Problems with false results of HIV testing have already been discussed. It is important to remember that as the prevalence of the virus in the population tested declines, the proportion of false results increases. Thus, how much of a risk one encounters in being falsely labeled HIV positive is dependent on many variables.

Issues of privacy and confidentiality are intimately involved in HIV testing. Many states are considering legislation that would identify and track both victims of the disease and carriers of the virus, even though the Centers for Disease Control have labeled this a costly and intrusive mistake (Gruson, 1987). The California Medical Association voted in March, 1987 to support a proposal that would allow doctors in that state to tell the spouses of carriers of the HIV about their partner's antibody status. And in Illinois legislation already being considered, physicians, hospitals, laboratories, blood centers and other health care centers would be required to report the names of HIV carriers to the state, in addition to providing the names to school officials and employers.

Finally, other uncertain risks are present. Public officials have called for the quarantine of infected persons (Hagen et al., 1988). School boards have barred seropositive children from the classroom. Ministers have excluded infected children from the church (Gianelli, 1987). Some medical personnel have refused to provide care to infected patients (Richardson et al., 1987). How people will respond both to the reality of this disease, and the fear and panic which encumbers it, has yet to be completely seen.

III. AN EMPIRICAL STUDY OF INFORMED CONSENT AND HIV TESTING.

A. INTRODUCTION.

The purpose of this study is to investigate the nature of informed consent as it is used in conjunction with HIV testing at the Yale-New Haven Hospital (YNHH). Before HIV tests are performed at the YNHH central laboratory facility, physicians must certify in writing that patient consent has been obtained. This provides an ideal setting to assess exactly what information physicians feel is necessary to disclose to obtain valid patient consent.

One of the legal standards for consent relies on the "community of physicians" to determine what information should be disclosed. Does such a standard exist for HIV testing? Are physicians uniformly discussing the benefits, risks, and negative consequences of such testing? The determination of a standard of disclosure for HIV testing was a major goal of this study.

An additional benefit of the investigation was the profiling of HIV testing as it is performed at YNHH: How often is the test being used? By how many physicians? What spectrum of physicians is using the test, and for what purposes?

Finally, the study would possibly heighten the awareness of those physicians using the HIV test.

Physicians, through their interactions with the investigator, would be made more conscious of the attendant benefits and risks of HIV testing, and therefore would be more likely to treat their subsequent disclosures with this information in mind.

B. LITERATURE REVIEW.

The review of the pertinent literature will consist of two parts: first, a review of the major empirical studies dealing with the more general issues of informed consent; and, secondly, a review of empirical assessments of the attitudes and behaviors of health professionals in their interactions with AIDS patients.

1. A REVIEW OF EMPIRICAL INFORMED CONSENT STUDIES.

One author has described four elements necessary to a valid informed consent (Beauchamp & Childress, 1983): 1. Disclosure of information; 2. Comprehension of information; 3. Voluntariness of consent; and, 4. Competence to consent. Empirical studies on consent have focused on two of these elements: namely, the disclosure and comprehension of information. Each of these, in its own right, is available to empiric study.

Thus, studies on the practical use of informed consent are centered on either physicians alone - what they are saying to patients - or on patients alone - what they are understanding of what has been told to them. There are few parallel studies that attempt to look at both disclosure and comprehension at the same time.

This review will therefore concentrate on the landmark studies in each of the these three relevant categories: 1. Studies focusing on physician disclosure; 2. Studies focusing on patient comprehension; and, 3. Studies focusing simultaneously on physician disclosure and patient comprehension. Empirical studies in some of these categories are limited both in number and scope (Miesel & Roth, 1981), and are therefore included primarily for historical and methodological interest.

a. Studies focusing on physician disclosure.

Hershey (1969)

Published in 1969 as a research monograph by Nathan Hershey and Stanley Bushkoff of the University of Pittsburgh, this study is important primarily because it is the first systematic attempt to investigate disclosure practices, and it thus pioneered much of the methodology that is used today.

The study was divided into two parts. In the first, a questionnaire on hypothetical patients requiring two separate orthopedic procedures was given to 22 surgeons known personally to the author. Eleven of the 22 responded. Using this group as a "test" population, the authors, in the second part of the study, sent out a large number of created consent forms to surgeons at six institutions. The consent form, which was to be completed at the time the surgeon obtained consent, included questions about the purpose and nature of the contemplated procedure, the risk and benefits of the procedure, and a separate consent for the administration of anesthesia. Usable responses were obtained from only ten surgeons from a single institution, representing a total of 256 patient encounters.

No definite disclosure pattern was evident from the results of the preliminary investigation. The second study yielded the following results: 1. A fairly consistent standard of disclosure already existed amongst surgeons, to

a greater extent than they realized or admitted; 2. Disclosure practices that used a consent form similar to the one used in the study would not lead to an interminable question and answer session between surgeon and patient; 3. Patients would not be upset by the disclosure process and the consent from, leading to refusal of the proposed surgical treatment; and 4. Adequate disclosure is not a time consuming process, and that, "for the majority of patients, the disclosure process...can be completed in less than ten minutes." These questions were important as the use of standardized consent forms had just begun.

Given the poor response rate from the surgeons approached by the investigators, few reliable conclusions about the actual practice of informed consent can be drawn. The primary contribution of the study has been its investigation of the methodologies available for the empirical study of informed consent. Succeeding studies (Rosoff, 1976) have used this study as a guide, and in many ways, it serves as a model for the present study on HIV testing and informed consent.

Hagman (1970)

Donald Hagman, a professor of law at UCLA, distributed a questionnaire containing nine hypothetical cases to all registrants for a series of seminars held by the UCLA Schools of Law and Medicine. Following each case, a series of questions was posed: Was the resolution of the case

proper as a matter of good medical practice? As a matter of ethics? As a matter of law?

Similarly, questionnaires were sent to 300 physicians in Minnesota, and to 400 physicians in California. Not all questionnaires contained the same hypothetical cases. For each of 26 cases presented, the number of total respondents (from the seminars, from Minnesota, and from California) varied from 34 to 184.

Hagman's interest in the study lay in determining whether legal proscriptions for physicians' behavior in obtaining informed consent were at odds with good medical and ethical practice. He concluded that they were not. In addition, he concluded that the law did not cause "bad medicine", but that disclosures that were medically sound were also legally acceptable.

This study highlights some of the problems in informed consent research, i.e. the difficulty in obtaining a representative study sample, and the difficulty in ascribing conclusions to data collected from a large, non-uniform series of hypothetical cases. In addition, this study measures, as hypotheticals do, what an actor would do, rather than what was actually done. Physicians' attitudes toward disclosure, rather than physician behavior, were the true subjects of this study.

These two studies, therefore, are significant primarily for their introduction of two methods of study to the field of informed consent: 1. The use of self-administered

questionnaires; and 2. The use of hypotheticals in assessing physician behavior. The actual results of the study are of limited interest, given the low response rate and the changing legal nature of the doctrine since that time.

The final study investigating the nature of disclosure is a much broader and ambitious project with more reliable results. Many features of this study, such as the use of a ranking scale to study frequency of disclosure of specific items, were used in the current study.

Rosoff (1976)

A much larger scale study of physician practices in informed consent was undertaken by Arnold Rosoff of the University of Pennslyvania in 1976. In this study, a questionnaire containing 39 questions relating to informed consent was sent to physicians of two specialties (internal medicine and surgery) in certain purposefully selected states (Pennsylvania, New Jersey, Arizona, Delaware, Kansas, California, Rhode Island, and the District of Columbia).

The questionnaire asked physicians about the frequency with which they discussed 21 areas of treatment information with their patients, including such basic legal components of informed consent as the diagnosis, the nature of the procedure, the risks and benefits of the procedure, and the alternatives to the procedure. The frequency of discussion

of each item could be recorded as: always, usually, rarely, or never.

As expected with this type of study, Rosoff obtained a low response rate of 24%, and thus was unable to make any claims that the sample represented the "typical American physician". Physicians reported that they very frequently would disclose to patients those items that the law would regard as mandatory subjects of disclosure.

Grouping together answers of "always" and "usually" as "commonly disclosed", the survey found that: 1. 98% of responding physicians reported commonly disclosing the diagnosis and prognosis of a patient's condition; 2. 99% the nature or purpose of the recommended treatment; 3. 91% the risk attending the procedure; and 4. 87% the negative consequences or side effects that are certain or fairly likely to attend the proposed procedure.

Given these impressive figures, one must look closely to how the data were obtained. In this case, a small number of highly motivated physicians (who are, perhaps, more motivated in discussing informed consent with their patients) completed a lengthy questionnaire. And again, as in the Hershey study, what is being measured is not what physicians, in fact, did, but rather, what physicians say they did.

Nevertheless, the Rosoff study represented a major leap in informed consent research: it attempted, on a national scale, to assess the effect of the evolving legal doctrine

of consent on actual physician behavior. This study set a new standard in scope, in detail, and certainly in ambition.

b. Studies focusing on patient comprehension.

Robinson (1976)

This is an example of a study designed to assess what patients recall of a relatively standardized disclosure. Dr. Gregory Robinson, a surgeon in private practice in New York City, tape-recorded informed consent disclosure conversations with approximately 200 of his patients. His associate, Dr. Avram Merav, questioned selected patients from this group some four to six months later as to their recollection of the disclosure conversation.

Patients were found to have remembered spontaneously only 29% of the substance of the disclosure. This figure rose to 42% when patients were prompted with particular details.

Although centered on the comprehension element of informed consent, this study presents a unique and useful method for the empiric assessment of disclosure - the tape-recording of actual disclosure conversations. The perceived intrusiveness of this method, however, would limit its applicability.

Alfidi (1971,1975)

Also pertaining to the patient's comprehension of disclosure elements, these two studies were designed to investigate patients' reactions to the disclosure of risks associated with angiography.

A total of 232 patients referred for angiography (of any vessel) were given a short questionnaire that accompanied the explicit disclosure for angiography. The results from this questionnaire showed that, for a large number of patients, the explication of risks pertaining to a procedure made them more comfortable with going ahead with that procedure. A small number of patients (2%) refused the procedure after the presentation of its attendant risks.

Alfidi concluded that the fear that patients would become uncomfortable or refuse procedures if given all pertinent risk information was largely unfounded, and that in fact patients became more comfortable with more information.

The companion study, in 1975, assessed whether patients, after having been informed that a procedure had "significant hazards associated with it," would desire further information regarding those hazards. The results of this study contradicted the 1971 study in that 176 of 275 patients declined further information about risks.

Alfidi concluded that the difference was primarily in how risk information was presented: if patients are given

this information, they are glad for it; if they must ask for risk information, they would rather not have it.

Rosenberg (1973)

Another investigation of patients' attitudes toward disclosure was undertaken by Sidney Rosenberg of the Permanente Medical Group in San Francisco, who polled 100 of his patients whether disclosure of risks and negative consequences of a cerebral arteriogram would cause them to refuse the procedure. Rosenberg's patients answered this in the hypothetical, none of them ever having had to actually consider the procedure.

Similar to Alfidi's results, Rosenberg found that 73 of the 100 patients felt full disclosure to be desirable, but a full 50% of the patients said that they would have refused the procedure on the basis of the information provided. This startling result (in contrast to Alfidi's 2% of patients refusing angiography) is probably due to the fact that none of these patients were actually facing the necessity of having a cerebral arteriogram performed, or, perhaps, to the perception that the procedure would involve a vulnerable body part, namely, the head.

These three studies point out the limitations in studying patient comprehension before physician disclosure is adequately assessed. In the Robinson study, it is hard to know how standardized the disclosures were; the contradictory results in the Alfidi study lead us to

question how much patients comprehended what was being told to them; and in Rosenberg's study, we are left with a distinct feeling that facing a "hypothetical" procedure is nowhere near analogous to what happens inside the mind of a patient facing an actual medical emergency. Because of these limitations, the stage had been set for an attempt to study both disclosure and comprehension.

c. Studies focusing simultaneously on physician disclosure and patient comprehension.

Harris (1982)

Similar to the Rosoff study in scale and scope, this survey represents the first attempt to obtain a national composite picture of how physicians are behaving within the changing legal status of informed consent.

Conducted by telephone interview, this survey, which was undertaken by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research and conducted by the Louis Harris Agency, polled a carefully drawn, nationally representative sample of 805 physicians and 1,251 members of the general public. Telephone interviews were completed with 68% of the eligible physicians, and 70% of the eligible households that were reached during the period of the study, a response rate significantly higher than in previous studies.

The design of this study differed in a few ways from the previous study by Rosoff, although the approach is primarily the same. A split format was used: that is, the sample was divided in half, with each half answering primarily the same questions, but with different ranking scales or answer choices. Thus, one question "In your practice, how often do you discuss each of the following things with the patient -- always, usually, sometimes, rarely, or never?", asked to half of the physicians became "In your practice, do you initiate discussion about each of the following things with the patient as a matter of course, or discuss it only if the patient asks about it?" for the other half.

Another change from the Rosoff study was the expansion of the number of response categories from four to five (Always, usually, sometimes, rarely, or never) which the authors felt removed pressure on the physicians to answer on either end of a continuum.

The results of the Harris study confirmed what was found by Rosoff in 1976: physicians report a very high level of disclosure on most items that the law mandates. Harris found that 98% of physicians reported disclosing the diagnosis and prognosis of a patient's condition; 96% disclose the nature and purpose of the proposed treatment option; and that 93% disclose negative consequences that are certain or fairly likely to ensue.

In addition, Harris asked the population sample about the frequency of discussion of certain treatment risks, which varied by probability and seriousness of outcome. For risks of serious disability or death that occur in 1 out of 100 cases, 82% of physicians reported disclosure. Fifty-nine percent reported they commonly disclose risk of death or disability that occur in 1 out of 1000 cases. And, finally, 57% of physicians report disclosing risk of temporary disability that are about 1 in 1000.

As Faden and Beauchamp (1986) have noted, the results of the Harris study give the impression that obtaining informed consent has become a routine component of American medical practice, particularly for invasive medical procedures. Significant to the present study, only blood tests and perscriptions were found to proceed without patient consent, although about half of the physicians reported obtaining oral consent for these also. Compared with the study by Hershey in 1969, we see how medical practice has evolved in such a short time to match the public and legal expectation for improved physician communication.

2. EMPIRICAL STUDIES ON THE ATTITUDES AND BEHAVIORS OF HEALTH CARE PROFESSIONALS ON ISSUES SURROUNDING AIDS.

The second part of this literature review consists of an overview of the major studies looking at the behavior and attitudes amongst practitioners who treat AIDS patients.

a. Studies on attitudes of health care workers.

In July 1987, a provocative study of medical students' attitudes toward AIDS and homosexual patients appeared (Kelly *et al*, 1987). Medical students are often chosen as a study sample for investigations of health professionals' attitudes given their relative accessibility and willingness to participate.

In this study, 119 second-year students at the University of Mississippi School of Medicine were presented with four patient vignettes, identical in content with the exception of the identification of each patient as having either AIDS or leukemia, and as either homosexual or heterosexual. Only one of the possible four combinations of patient characteristics was presented to each student. Students then completed a 12-item prejudicial evaluation scale, rating their responses on a 7-point Likert scale (from 1=strongly disagree to 7=strongly agree).

The authors showed that medical students view AIDS patients in a highly negative manner, as they do homosexual

patients, regardless of illness. Homosexuals were viewed as being more responsible for their illness, ($p<0.005$); more dangerous to others, ($p<0.05$); and suffering less pain than the heterosexual patients, ($p<0.05$). The students believed that the AIDS patients were more deserving than leukemia patients of their illness and more deserving to die, to lose their jobs, and to be quarantined.

In concluding, the authors expressed alarm at the degree of negativity expressed by the students toward certain patients, and contemplated the implications of this on future health care quality.

A similar study was undertaken by Koenig & Cooke (1987) of UCSF, who studied the attitudes of house staff directly responsible for the care of AIDS patients. Medical house officers of the San Francisco General Hospital were presented with a questionnaire addressing estimation of risk to health care workers, anxiety elicited in the treatment of AIDS patients, and satisfaction in the care of AIDS patients.

The results can be summarized as follows: 1. Risk - Sixty-eight percent of respondents felt that health care workers were at some risk of contracting AIDS, with the male respondents considerably more concerned about this possibility (84% vs. 48% of women). 2. Anxiety - The authors found that at least 80% of the medical house staff were "mildly anxious" about treating AIDS patients, and 20% labeled themselves as "very anxious". Twenty percent

reported dreams or nightmares about AIDS, and 18% reported symptoms which they felt were suspicious of AIDS.

3. Satisfaction - Results from this category clustered around the mid-point of a 4-point Likert scale. The amount of satisfaction obtained from treating AIDS patients was found to be inversely proportional to the amount of AIDS treatment experience. Koenig and Cooke concluded with a call for more assistance to health care professionals in the stress induced by assuming their responsibilities in caring for patients with AIDS.

b. Studies on physicians' behavior regarding HIV testing.

Finally, the results of a study very similar to the present one appeared recently (Henry *et al*, 1988). The clinical use of the HIV antibody test at a single institution affiliated with the University of Minnesota Medical School was investigated, with particular attention paid to the whether the test was medically indicated, whether informed consent was obtained, and whether risk-reduction counseling took place.

All of the HIV antibody tests ordered through one medical center from April 1985 through August 1986 were studied. In addition to obtaining basic demographic information about both doctor and patient, the investigators examined chart notes for documentation of consent and

discussion of risk-reduction. In addition, a judgement concerning the "appropriateness" of the testing was made, using Minnesota Department of Health guidelines, which included the presence of risk factors and completion of counseling and consent procedures as minimum requirements.

Results were tabulated for all 275 patients for which HIV antibody tests were ordered during the data collection period. Certain results are particularly important to the current study: Fifty-eight percent of charts presented a rationale for the ordering of the test; Twenty-one percent of charts made mention of the fact that the test was discussed with the patient; Nine percent of charts documented that discussion and risk-reduction counseling had occurred; Three percent of charts contained a patient-signed consent form. Patients who had been tested while on a surgical service were less likely than those on a medical service to have a note in their chart referring to the test. As to the appropriateness of HIV antibody test ordering, only 10% of the tests were found to have been "appropriately" ordered, a statistic that did not vary by care provider characteristics (gender, race, or level of training).

Unfortunately, there is no mention of what constitutes informed consent in the charts of patients for whom consent was obtained. The authors urge that the reason for ordering the HIV antibody test and the patient's consent need to be documented, but again, no mention is made of what this

actually means. Certainly, the mere presence of a written statement that consent was obtained by the ordering physician does not guarantee that the patient was informed of - or understands - the nature, risks, benefits, and negative consequences of the test to be employed. The goal of the present study is to investigate what is considered, by ordering physicians, to be informed consent for HIV antibody testing.

C. METHODS.

Requests for HIV tests are submitted to the Yale-New Haven Hospital Blood Bank on a standardized order form (Anti-HIV, form #F-3196, Stock #66785 - See Appendix B.) which includes the name of the patient, the name of the ordering physician, the reason for the test, and the signature of the responsible physician certifying that consent has been obtained.

Names of physicians who ordered tests between March 7, 1988 and March 21, 1988 were obtained from the chief technologist, along with the date of the test, and the reason for the ordering of the test. As indicated on the test form, reasons for test ordering are divided into five categories, and these were obtained from the laboratory as #1-#4, or "other". Human Investigations Committee approval was requested and granted, pursuant to the stipulation that no patient names be recorded.

Inhouse ordering physicians were contacted by telephone and asked to sit for a fifteen-minute semi-structured interview (Appendix A). Physicians ordering more than one test during the stated time period were interviewed regarding their most recent patient disclosure conversation.

Interview results were compiled anonymously, tabulated, and analyzed using the SAS package at the Yale University School of Epidemiology and Public Health (Ray, 1982).

D. RESULTS

1. PROFILE OF TESTING OVER THE SAMPLING PERIOD.

Over the period from March 7, 1988 to March 21, 1988, a total of 107 HIV tests were ordered through the Yale-New Haven Hospital testing facility. As this laboratory provides testing to services to outside laboratories and private physicians, this total can be further subdivided into 46 (43%) inhouse tests ordered, and 61 (57%) outside test requests.

A total of 28 inhouse physicians were responsible for the 46 tests ordered: of these, 20 (71%) ordered only one test. Four physicians ordered three or more tests during the testing period.

2. DEMOGRAPHIC PROFILE OF THE PHYSICIAN SAMPLE.

Of the total of 28 physicians ordering tests during the sampling period, 20 (71%) were interviewed. Of the eight physicians not interviewed, six were repeatedly unavailable, one did not directly obtain consent (a designated subordinate, whose name could not be ascertained, was responsible for this), and one physician's name was illegible as written on the test order form.

Tables 1 and 2 summarize the demographic characteristics of the study sample. In summary, the typical ordering physician tended to be male (70%), to be an internist (50%), to be a house officer (50%), to be between the ages of 30 and 39 (65%), and to have one to ten years of clinical practice experience (75%).

3. RESULTS OF THE "SPECIFIC CASE" QUESTIONS.

a. The reason for test ordering.

Generally, the reason for test ordering stated by the physicians corresponded with the reason indicated on the Anti-HIV test order form (see Table 3). The categories listed on the order form are broad enough to cover most indications for ordering an HIV test. Two (10%) physicians described the reason as "screening", a category not available on the test order form. Other reasons given were: "...the patient had recently returned from Africa" and had requested testing; a "patient's partner was snorting coke" and the patient had requested testing; a "patient's boyfriend had hepatitis B" and had requested testing; and "testing is a criterion for participation in a research project".

The majority of tests were ordered in the outpatient setting (85%), and were commonly the first test ordered for that patient (85%).

b. The purpose of HIV testing.

Answers to the question "was the purpose of the test explained; that is, what the test will actually do?" are found in Table 4. Only one (5%) physician reported not explaining the purpose of the test to the patient. The purpose for HIV testing most commonly explained to patients was to document previous exposure to the HIV (50%). Other purposes stated included: "to rule out the presence of the virus", and "this is an AIDS test".

c. Other benefits of HIV testing.

Five (25%) respondents reported explaining other benefits of HIV testing to the patient (see Table 4). Cited benefits included: "to put one's mind at ease"; "important diagnostically"; "helps narrow down diagnostic possibilities"; "could be important therapeutically should she decide to get pregnant"; and, "if positive, the patient could be counseled".

d. Risks of HIV testing.

Six (30%) of the responding physicians reported that they had explained the risks of HIV testing to the patient (see Table 4). Those risks discussed included: "the same risks as other blood tests"; "the uncertainty of what a positive result means"; "the possibility of discrimination"; "the possible loss of confidentiality";

"the anguish over a false-positive result"; and, "possible changes to one's sex life".

e. Additional information requested by the patient.

Additional information was requested in five (25%) cases (see Table 4). These items requested included: "how long will the test take?"; "is the test confidential?"; "what are the alternatives?"; and, "does this mean that I have AIDS?".

4. RESULTS OF THE "USUAL PRACTICE" QUESTIONS.

The results of questions in section 4 of the survey instrument are found in figures 1 and 2, and in Table 5. Figures 1 and 2 show the frequency of disclosure of the suggested benefits and risks queried in section 4. For these purposes, answers of "always" and "usually" were combined as "commonly disclosed", and answers of "sometimes" and "never" were combined as "commonly not disclosed". Figures 1 and 2 show the percentage of respondents who reported "commonly disclosing" the listed benefits and risks.

A "disclosure sum" was calculated for each respondent using numbers assigned to each of the four possible answers: "always"=3, "usually"=2, "sometimes"=1, and "never"=0. Thus, the "disclosure sum" for a particular physician may

range from 0 (where every benefit and risk was reported as "never" being disclosed) to 48 (where every benefit and risk was reported as "always" being disclosed). The "disclosure sums" are listed in Table 5.

Multiple regression analysis was used to analyze the variance in the "disclosure sums". The predictive value of age, sex, clinical practice experience, HIV test ordering experience, and location of test ordering on the "disclosure sum" was assessed. None of these variables were found to predict significantly ($p<0.5$) the variance in the "disclosure sum".

E. DISCUSSION

1. FORMULATION OF THE SURVEY INSTRUMENT.

As mentioned previously, few empirical studies of informed consent have attempted to discern what physicians are actually saying to patients in their disclosure conversations. Miesel and Roth (1983) noted:

> It is therefore regrettable that so few investigators have undertaken a study of these matters. Worse, however, is that knowledge of what patients are told is an antecedent condition to the knowledgeable study of what patients understand, how they make decisions, and the degree of voluntariness with which those decisions are made. It is difficult, if not impossible, to evaluate other aspects of informed consent without knowing first what patients are told.

The aim of the current study is to investigate the nature of physician disclosure practices when ordering HIV antibody tests in the hospital or clinic. Three of the previous studies provided a methodological history whereby an instrument for obtaining data from physician-patient conversations could be formulated (Hershey, 1969; Rosoff, 1981; and Harris, 1982). In two of these studies, Hershey (1969) and Rosoff (1981), a self-administered questionnaire was used, while in the third, Harris (1982), a telephone interview survey (in a format very similar to the previous questionnaires) was used. In two of the studies, Rosoff and

Harris, questions were asked regarding the frequency of discussion of certain items in the disclosure conversation using either a four-point or a five-point response scale. With the exception of the Harris study, all of the previous studies have been plagued by a small response rate, either because of the threatening nature of the subject explored, or the burden in time and effort of the particular survey method employed.

Thus, it became apparent that the survey instrument used in the current study must meet, at a minimum, three goals: 1. Brevity - Given the poor response rate associated with long, detailed questionnaires, it seemed imperative to keep our questioning format concise and focused. Since we were interested in only a single use of informed consent, this could be more easily achieved; 2. Immediacy - To prevent the introduction of error due to loss of recall, it was desirable to question physicians as soon after the disclosure conversation as possible; and 3. Anonymity - The discussion of issues surrounding AIDS is a sensitive one for physicians and patients alike, and the information obtained must be designed so that no particular physician could be identified.

Since a higher response rate was obtained through the use of physician interviews (Harris), and physicians would be more likely to recall the events of a disclosure conversation in an immediate interview, I decided that a

semi-structured interview would be the format most likely to quickly obtain accurate data.

Through contact with Yale-New Haven Hospital's HIV testing facility, ordering physicians' names were obtained, and immediate contact with a request for a short interview made. Rather than depending on physicians to complete a self-administered questionnaire - a factor that, in addition to complicating the logistics of data collection, distorts the nature of the physician sample - the proposed method would allow physicians to make an immediate decision regarding participation.

Using an interview format, I envisioned a greater willingness on the part of physicians to participate. In addition, this eliminated mailings or written documents linking physicians' names to data, thereby better insuring anonymity. The three goals of brevity, immediacy, and anonymity seemed best served with a semi-structured interview format.

The first part of the interview, following the example of many previous studies, consisted of questions designed to gather basic demographic information on the study sample. As in Koenig & Cooke (1987), Rosoff (1981), and Henry *et al.* (1988), data on the physician's age, gender, specialty, experience, and practice type would be obtained. Previous differences in physician behavior patterns according to the gender, specialty, and experience of the physician involved, had been clearly demonstrated.

A competing goal, the anonymity of the physician, is threatened by questions of this type, and thus the complete elucidation of physician characteristics had to be avoided (Appendix A, section 2.). A statement guaranteeing confidentiality was included before the interview began to insure the voluntary and frank participation of the physician sample.

In designing the content of the physician disclosure conversation itself, two pitfalls were to be avoided: the unnecessary prompting by the questions themselves, such that physicians were answering what they "ought" to have done rather than what they actually did; and limiting the format to only open-ended questions on the specific disclosure conversation at hand, so that no true picture of this particular physician's behavior for all such cases could be assessed.

Therefore, the first group of questions was designed to discover what was relayed in a particular disclosure conversation to a particular patient regarding the basic legal components of consent (the nature and purpose, risks, benefits, alternatives and negative consequences of the proposed procedure). The physician would have the opportunity to relate what was actually told to this patient.

Then, in a quantifiable way, several questions were asked on recommended components of an HIV antibody disclosure conversation, thereby determining the frequency

with which physicians included these components in their conversations (Appendix A, section 4.). Using a four-point response scale similar to Rosoff (1981), we would then be able to draw a picture of what components are most frequently considered necessary for informed consent. See Goldblum & Seymour (1987) for these recommended consent components. Correlations based on the demographic information gathered in section 2 could then be made with this data.

Finally, a block of time would be reserved at the end of the interview for any additional comments that the physician might want to make.

Since we could not actually study the disclosure conversation as it actually occurred, we were left with the major drawback of depending on physicians' perceptions of what they have told to patients. While I have no reason to conclude that physicians would deliberately misrepresent what occurred, one can not be assured, without recording the conversation itself, that what was obtained was accurate information about the content of the disclosure conversation. This study is therefore limited to studying what physicians say they did, rather than studying what they actually did.

Another methodological problem is the possibility that those willing to participate in a short interview might not, in fact, be representative of the physician population at large. Those physicians willing to donate their time for an

investigation into informed consent may be biased in favor of providing more thorough disclosure conversations to their patients.

Thus, the final survey instrument consisted of a semi-structured interview of three parts: 1. Demographic information of the respondent; 2. Open-ended questions on the disclosure conversation that pertained to a particular patient; and 3. Specific questions on the usual practice of the physician when obtaining consent for HIV testing. In this way, the broadest profile of physician behavior in obtaining consent for HIV testing could be studied.

2. DISCUSSION OF INTERVIEW RESULTS.

Although this study is meant primarily to be an exploratory study of the decision-making process in HIV testing, some conclusions can be drawn from the numerical survey results.

First, the results from the "specific case" questions (Table 4) show a surprising underreporting of many of the suggested items of disclosure. Not even half of the interviewed physicians reported disclosing the relevant benefits and risks of the procedure, and few of their patients requested any additional information. The most frequently disclosed item was found to be the purpose of the HIV test (reported by 19 of 20 physicians), and there seemed

to be a fair amount of uniformity in what this was thought to be (50% of the disclosing physicians described the purpose as documenting exposure to the HIV). Contrary to the published advice of experts, one physician reported the purpose as "an AIDS test", which may lead to further misunderstanding on the part of the patient.

This survey was designed so that physicians would spontaneously report what they considered the risks and benefits of HIV testing to be, before being prompted by the suggested risks and benefits in section 4. Some of those suggested items were reported by physicians as being disclosed to their patients: the alleviation of anxiety, the test's use as a diagnostic tool, the problem of false results, and the psychological trauma that accompanies testing. Still, the results of section 3 generally show that patients are not being made explicitly aware of the benefits and risks of HIV testing. It would be hard, given this lack of disclosure, to construe that the consent that patients are giving is "informed".

The results of the "usual practice" questions show the same underreporting of risks and benefits as a general rule in the practice of these physicians. Only one suggested benefit of HIV testing was reported by more than half of the physicians interviewed (the use of the test as a diagnostic tool).

One of the benefits listed, the possibility of protecting the staff of the hospital from infection, is not

one of the suggested benefits of Goldblum & Seymour (1987), but was asked to determine whether physicians were routinely ordering HIV tests for this purpose (or at least informing patients that they were ordering for this reason). Only 20% of the respondents reported commonly disclosing this information. Experts have advised against the use of the HIV test for this purpose (Bayer *et al.*, 1986).

Generally, the risks of HIV testing, including the more catastrophic consequences of loss of employment and insurance, are not being disclosed. Only one risk was reported by more than half of the physicians as being commonly disclosed: the possibility that the test results may be false. One physician expressed the belief that the HIV test was a "no risk" procedure and should be performed without any patient consent.

The "disclosure sum" indicates that physicians, in their usual practice, are underdisclosing. With an "average" disclosure earning a score of 24, only three of the 20 physicians had this score or above (see Table 5). In fact, the majority of physicians (65%) had scores of 14 or below. Again, most of the suggested benefits and risks are not being disclosed.

One of the more striking general conclusions about the use of the HIV test at the Yale-New Haven Hospital is the variety of clinical situations in which the test is used and the implications that this has for the standard of informed consent. Since the test is used in inpatient and outpatient

settings, in research studies and clinical use, for specialized procedures (*e.g.* organ donation) and for routine diagnostic workups, many physicians expressed the belief that they were not using the test for the purpose it was created. The implications of this on disclosure were significant: many felt that full disclosure, given their special setting, was unwarranted.

Not all of those interviewed were physicians. Three of the respondents were nurses and had received previous permission to sign a designated physician's name certifying that consent had been obtained. Given the small number involved, it is hard to assess how this may alter the consent process. One physician who had been asked for an interview stated that he never actually obtained the consent, and that there were many designated subordinates who were responsible for this. Whether nurses are more likely to disclose more information in their conversations is unclear from the data, but given the legal responsibility of the physician whose name appears on the order form, it would behoove physicians to be aware of and change, if necessary, what is being told to patients.

Several observations on the process of decision-making in HIV testing can be made. First, the content of counseling and consent for HIV testing seem to overlap. What constitutes minimum disclosure for consent, many physicians would include in their counseling session with the patient (either before or after the test had been

ordered). Many physicians reported that some of the risks of testing would be disclosed or discussed upon the presentation of a positive result. Even though the test results may remain confidential, the patients, in these instances, are being effectively excluded from the decision-making process itself.

Another general observation was that physicians would make certain assumptions about their patients' level of competence and understanding, and these physicians would base their disclosure on these assumptions. If patients are assumed to be incapable of understanding the ramifications of testing, it is ironic that less rather than more information is disclosed.

Many physicians reported not disclosing the problems of employment and insurance because they assumed their patients did not have jobs or insurance to begin with. In the inpatient setting, where physicians may have had very little previous contact with their patients, physicians may actually know very little about their patients' job or insurance status. The consequences of these assumptions may be devastating. Outpatient disclosures, given the above reasoning and perhaps more lenient time constraints, tended to be more complete.

Many physicians made the comment that their patients had requested the test, and they adjusted their disclosure patterns appropriately. The more the patient had desired the test, the less discussion was deemed necessary. Whether

the physicians felt that the patients already had risk and benefit information available because of their demonstrated interest in the test, or whether they were just complying with their patients' wishes is not known. Yet, demonstrated anxiousness or willingness to be tested prompted less information from the physician.

Physicians also adjusted their disclosure downward when they felt their patients had a low likelihood of testing positive. This included low-risk populations for research studies and organ donations. Since many of these physicians had not yet had to inform a patient of a positive result, many seemed to order the test with the assumption that the test result would be negative, and that, therefore, made disclosure of risk and benefit information unnecessary. Interview respondents who dealt with the HIV test for a specialized purpose (such as organ donation) felt that disclosure was necessary only for other more "routine" uses of the test. Some felt that I was talking to the "wrong" physician and should actually be speaking to a physician who uses the test for medical diagnosis and risk reduction counseling.

Similarly, one physician expressed the idea that since some patients were "responsible" themselves for having the disease, they "deserved" less information in obtaining consent. Thus, the more culpable one was considered in having contracted the disease, the less disclosure was seen as necessary.

A limitation of interview or questionnaire studies of this type was noted as the interviews progressed. An ideal doctor-patient relationship may not necessarily deal with the explicit transfer of items of information, but may encompass the gradual and extensive interchange which leads to an understanding of the patient by the physician, including informational needs. Thus, a greater understanding of the patient by the physician may require less explicit exchanges of information, and thus the type of disclosure implied by the survey instrument would be unnecessary. Knowledge of the patient's own feelings about benefits and risks and how they would affect the patient's life may indeed alter the level of disclosure deemed necessary by the physician. This is true of informed consent in any context.

In this perspective, the use of standardized informed consent forms can be seen to be counterproductive: the reliance on specific items of information precludes the general, and often subtle, acquisition of knowledge and understanding about the particularities of a patient. Lack of disclosure, as predicted by the survey instrument in this study, may therefore actually denote a higher appreciation of the benefits and risks involved in HIV testing, and a greater understanding by the physician of how these may impact on the patient's life.

F. RECOMMENDATIONS.

Since information is generally underreported to those patients considering HIV testing, several recommendations can be made to improve the quality of decisionmaking.

First, physicians need to be aware of the relevant risks and benefits of HIV testing, and they also need to know how these items of information apply to the varied clinical situations in which the HIV test is used. This study concluded that the HIV test inhospital is being used for many disparate purposes. Hospital policy can encourage standardization of the consent process by suggesting what should be considered minimum disclosure.

Given the social and political nature of some of these risks, it would perhaps be necessary to include non-medical personnel on any committee designed to set up a policy for informed consent in the context of HIV testing. Sociologists, social workers, clergy, and others will be more acquainted with the various social and psychological consequences of HIV seropositivity. Physicians can readily benefit from their expertise in these areas, and thus better inform their patients of the real risks of testing. Educational programs can be designed to acquaint physicians with the results of such policy decisions.

Accurate documentation of the consent process is integral to maintaining adequate levels of disclosure. Physicians should not merely record the fact that consent

has been obtained, but should outline what relevant issues were discussed. Quality control policies can be implemented that would monitor the level of disclosure by physicians.

Self-education regarding the indications and uses of the HIV test remains the cornerstone for altering the decisionmaking process. Physicians need to commit themselves to understanding the ramifications of HIV testing as it evolves over time.

Finally, government institutions need to be made aware of how the HIV test is being used in clinical settings, and to address their recommendations accordingly. Physicians need to be able to rely on realistic and concrete suggestions for improving the HIV test ordering process. Without direction, physicians will substitute their own ideas for what should be done, rather than relying on policy formulated by national experts in the field. Standardization can be achieved by bringing recommendations for physician behavior into line with the realities of clinical practice.

IV. TABLES AND FIGURES.

Table 1.

Demographics of the study sample: The gender, age, and clinical specialty of the interviewed subjects.

Gender	No. (%)
Male	14 (70%)
Female	6 (30%)

Age	No .(%)
20-29	4 (20%)
30-39	13 (65%)
40-49	1 (5%)
50-59	1 (5%)
>59	1 (5%)

Clinical Specialty	No. (%)
Internal Medicine	10 (50%)
Obstetrics/gynecology	3 (15%)
Nursing	3 (15%)
Surgery	2 (10%)
Dermatology	1 (5%)
Neurology	1 (5%)

Table 2.

Demographics of the study sample: The hospital affiliation, clinical experience, and HIV test ordering experience of the interviewed subjects.

Affiliation	No. (%)
House Officer	10 (50%)
Faculty	7 (35%)
Registered Nurse	3 (15%)

Experience Level	No. (%)
0 - 10 years	15 (75%)
11- 20 years	2 (10%)
21- 30 years	2 (10%)
31- 40 years	1 (5%)
Range	1 - 40 years
Mean	9.2 years

HIV test ordering experience	No. (%)
0 - 10 tests	9 (45%)
11- 20 tests	4 (20%)
21- 50 tests	3 (15%)
> 50 tests	4 (20%)
Range	1 - 160 tests
Mean	30.9 tests

Table 3.

Specific case questions: The reason for the test, the previous HIV testing history, and the origination of the test sample for the patient in question.

Reason (from Anti-HIV form)	No. (%)
Differential Diagnosis of Symptoms	7 (35%)
Asymptomatic outpatient for counseling	6 (30%)
Asymptomatic inpatient for counseling	0 (0%)
Organ/Blood/Tissue/Sperm donor	0 (0%)
Other[1]	7 (35%)

HIV testing history	No. (%)
No previous testing	17 (85%)
Previously tested	3 (15%)

Location of test ordering	No. (%)
Outpatient	17 (85%)
Inpatient	3 (15%)

[1]Listed under this category: "history of transfusion","needle stick","acute hepatitis","donor recipient","patient request", and "transplant patient".

Table 4.

Specific Case Questions:

1. "Was the purpose of the test explained to the patient; that is, what the test will actually do?"

Answer	No. (%)
Yes	19 (95%)
No	1 (5%)

2. "Were other benefits of having the test performed explained?"

Answer	No. (%)
Yes	5 (25%)
No	15 (75%)

3. "Were the risks of the test explained?"

Answer	No. (%)
Yes	6 (30%)
No	14 (70%)

4. "Did the patient request any additional information?"

Answer	No. (%)
Yes	5 (25%)
No	15 (75%)

Table 5.

"Disclosure Sum": A Measure of Physician Disclosure in HIV Testing.[1]

"Disclosure Sum"	No. (%)
0 - 8	6 (30%)
9 - 16	9 (45%)
17 - 24	3 (15%)
25 - 32	2 (10%)
33 - 40	0 (0%)
41 - 48	0 (0%)

Lowest possible disclosure sum -0[2]
Highest possible disclosure sum - 48[3]
Mean possible disclosure sum - 24[4]

Mean disclosure sum of interviewed physicians - 13.9

[1]The "disclosure sum" equals the sum of reported frequencies of disclosure of suggested benefits and risks of HIV testing, where Always=3, Usually=2, Sometimes=1, and Never=0. See Appendix A, section 4.
[2]Calculated as reporting "never" for each item of disclosure: (0 x 16 = 0).
[3]Calculated as reporting "always" for each item of disclosure: (3 x 16 = 48).
[4]Calculated as the mean of the lowest and highest possible disclosure sum: (0 + 48 = 48/2 = 24).

Figure 1. The percentage of respondents reporting "commonly disclosing" the suggested benefits of HIV testing. Responses to questions in section 4 of the survey instrument of "always" and "usually" have been grouped together as "commonly disclosed" and appear on the abscissa. The suggested benefits of Goldblum and Seymour (1987) appear on the ordinate:

1. Supporting or confirming a medical diagnosis.
2. Protecting the staff of the hospital from infection.
3. Reducing anxiety.
4. Motivating individuals to modify behavior.
5. Helping scientists to determine the extent of HIV infection.
6. Helping researchers to design experimental treatments.
7. Helping women at high risk to decide whether to become pregnant.
8. Helping women decide whether to breast-feed an infant, or to have an infant vaccinated.
9. Protecting the blood supply.
10. Ensuring that organ donations are safe.

Figure 1. "Usual Practice" Disclosures--Benefits

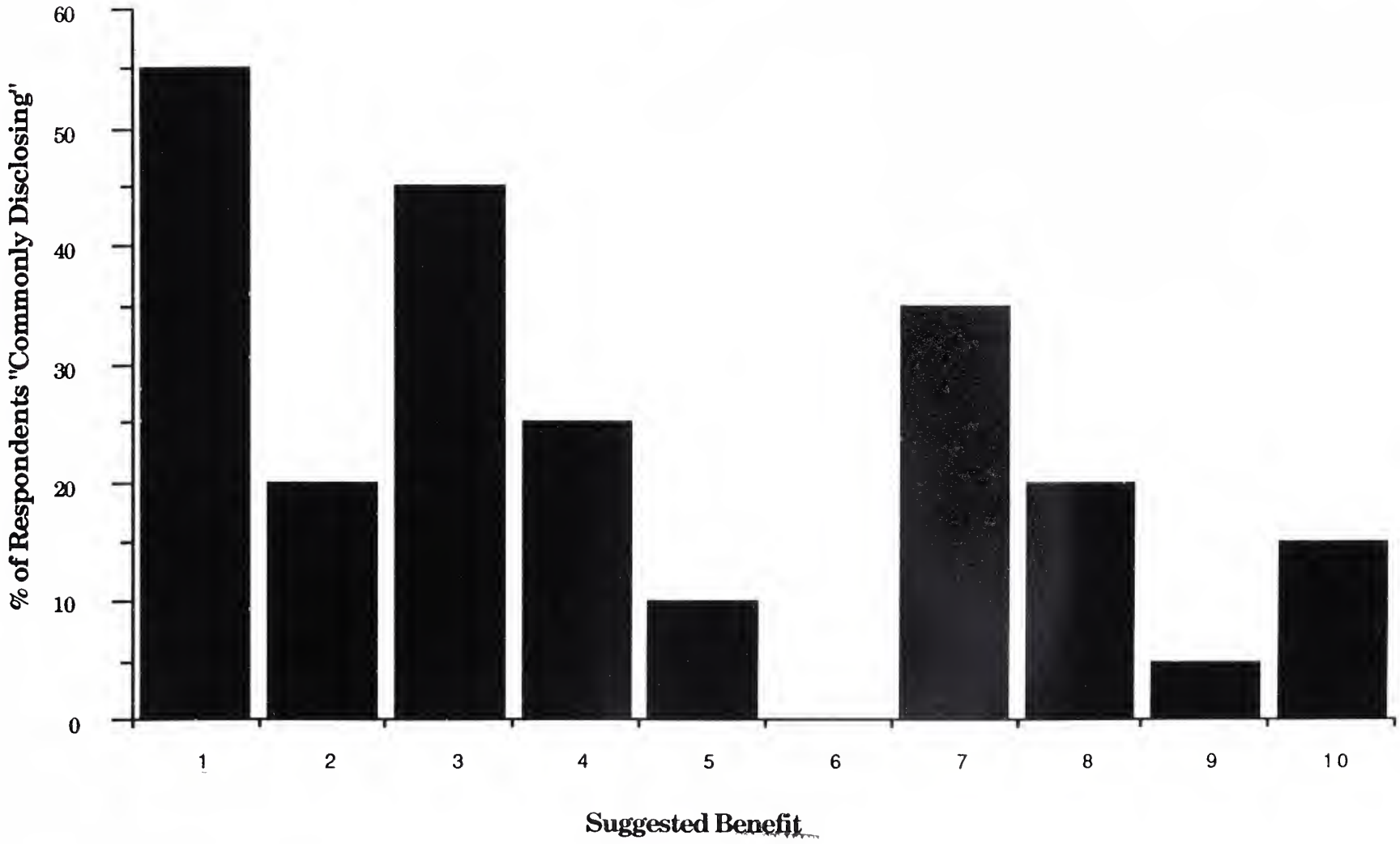
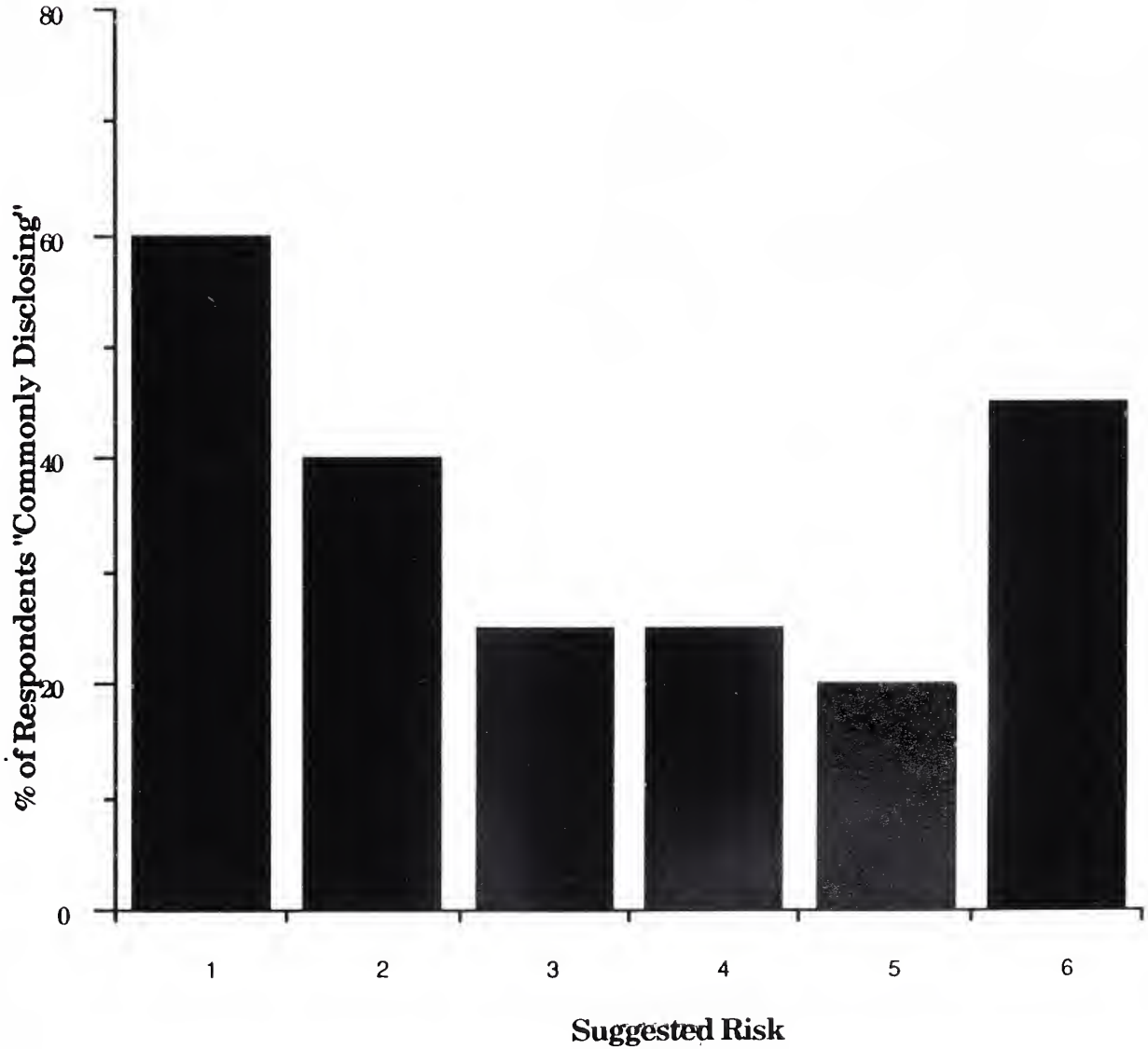


Figure 2. The percentage of respondents reporting "commonly disclosing" the suggested risks of HIV testing. Responses to questions in section 4 of the survey instrument of "always" and "usually" have been grouped together as "commonly disclosed" and appear on the abscissa. The suggested risks of Goldblum and Seymour (1987) appear on the ordinate:

1. Proving falsely positive or falsely negative.
2. Causing severe psychological reactions.
3. Disrupting personal relationships.
4. Causing problems with employment.
5. Causing problems with insurance.
6. Causing a false sense of security and denial if the test proves negative.

Figure 2. "Usual Practice" Discosures--Risks



V. APPENDICES.

A. APPENDIX A -- THE SEMI-STRUCTURED INTERVIEW.

1. STATEMENT OF CONFIDENTIALITY

This interview is completely voluntary and confidential. There are no markings or other devices by which I can identify any interview as coming from a particular physician. Your name will not be recorded. You are free to refuse to answer any question, or to terminate this interview at any time, and this will in no way affect your relationships with Yale-New Haven Hospital or Yale Medical School. I am not affiliated with either the laboratory performing these tests or any official of the YNHH medical center.

Please remember that it is the communication that you consider necessary for informed consent that I am interested in, and not risk reduction or other counseling information that you may convey to patients in the course of anti-HIV testing.

2. DEMOGRAPHICS

A. What is your age? (I am recording the decade only.)

B. How are you affiliated with YNHH? (HO, Faculty, Private MD only.)

C. What is your specialty?

D. How many years have you been in practice?

E. Have you ordered the HIV antibody test previously?

F. Approximately how many times?

G. Is this a first or repeat test for this patient?

H. Was this patient an inpatient or an outpatient?

I. Remember to record the person's age.

3. SPECIFIC CASE QUESTIONS

I am now going to ask some questions about the specific case for which you obtained consent. These questions will

apply to your conversation with this patient before the HIV test was ordered.

A. What was the reason that the test was ordered for this patient?

B. Was the purpose of the test explained; that is, what the test will actually do?

C. What did you communicate to the patient regarding the purpose of the anti-HIV test?

D. Were other benefits of having the test performed explained?

E. What did you communicate to the patient regarding the benefits of the HIV test?

F. Were the risks of the test explained?

G. What did you communicate to the patient regarding the risks of the HIV test?

H. Did the patient request any additional information?

4. USUAL PRACTICE QUESTIONS

I am now going to read a list of possible benefits and risks that can accrue from having the HIV antibody test performed. Drawing on all of the cases for which you have ordered the test, please tell the frequency with which you include the particular benefit or risk when you obtain consent. The ranking is:

Always Usually Sometimes Never

When you obtain consent, how often do you say "Testing for HIV antibody may help:"

1. to support or confirm a medical diagnosis.

2. to help protect the staff of the hospital and others from infection.

3. to reduce anxiety.

4. to motivate individuals to modify behavior.

5. to help scientists determine the extent of HIV infection.

6. to help researchers design experimental treatment.

7. to help women at high risk decide whether to become pregnant.

8. to help women decide whether to breast-feed an infant, or to have an infant vaccinated.

9. to protect the blood supply.

10. to ensure that organ donations are safe.

When you obtain consent for HIV testing, how often do you say, "Testing for HIV carries the risk of:"

1. proving falsely positive or falsely negative.

2. causing severe psychological reactions.

3. disrupting interpersonal relations.

4. causing problems with employment.

5. causing problems with insurance.

6. causing a false sense of security and denial if the test proves negative.

5. ADDITIONAL COMMENTS

B. APPENDIX B -- THE HIV TEST ORDER FORM.

ANTI-HIV – TEST CANNOT BE DONE WITHOUT COMPLETED SIGNED REQUEST

DATE: _____

AGE: _____ SEX: _____

M.D. ORDERING TEST: (PRINT)

_____

INDICATE REASON FOR TEST:

- ☐ DIFFERENTIAL DIAGNOSIS OF SYMPTOMS.
- ☐ ASYMPTOMATIC OUTPATIENT FOR COUNSELING
- ☐ ASYMPTOMATIC INPATIENT FOR COUNSELING OR INFECTION CONTROL
- ☐ ORGAN/BLOOD/TISSUE/SPERM DONOR
- ☐ OTHER _____

HAS PATIENT OR GUARDIAN CONSENTED? ☐ YES ☐ NO

IF NO, WHY?

BILLING/REPORTING INSTRUCTIONS IF REQUIRED:

IS CONSENT DOCUMENTED IN MEDICAL RECORD? ☐ YES ☐ NO

YALE-NEW HAVEN HOSPITAL PHYSICIAN SIGNATURE ONLY _____

EIA: ☐ POS ☐ NEG

RATIO: _____ Wb: _____

DATE: _____

YALE-NEW HAVEN HOSPITAL • 20 YORK ST. • NEW HAVEN, CT. 06504

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